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In re Application of	:
ARMOUR et al.	:Petition to Review Lack of Unity
Serial No: 09/674,857	:Under 37 C.F.R. 1.144
Filed: 7 November 2000	:
Attorney Docket No: 620-117	:

This is in response to applicant's petition under 37 CFR 1.144, 26 January 2004, requesting review of the Examiner's lack of unity requi rement mailed 6 December 2001. The delay in acting on this petition is regretted.

BACKGROUND

This application is a U.S. national stage application properly filed under 35 USC 371.

The Examiner instituted a lack of unity requirement that divided original claims 1-31 into 61 groups in an office action which was subsequently made final.

On April 11, 2003, in the response to the lack of unity requirement Applicant elected, with traverse, Group II, wherein the effector domain is the binding site of an antibody FOG1 capable of binding RhD. The examiner then considered the traversal, found it not persuasive and make the lack of unity holding final.

RELEVANT AUTHORITY

An international or a national stage application are considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2; 37 CFR 1.475(a), (b)(1) and (2).

PCT Rule 13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In addition to the categories provided for in 37 CF 1.475(b) (1-5), unity of invention is provided for in the following context:

> *Claim 1: Protein X*
> *Claim 2: DNA sequence encoding protein X.*

wherein expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity of invention between claims 1 and 2 is accepted.

See MPEP 1893.03(d) and Annex B, Part 2 of the PCT Administration Instructions, Example 17.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims and

> *(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;*
> *(ii) If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered. If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. See ANNEX B: Unity of Invention Part 1 "Instructions Concerning Unity of Invention" MPEP AI-6 (Rev. 1. Feb. 2003).*

DISCUSSION

Applicant's petition and the file record have been carefully considered.

Applicants are correct that the above-identified application is a national stage application submitted under 35 U.S.C. 371 to which "unity of invention", and not U.S. restriction practice is applicable. See MPEP section 1893.03(d).

Applicants have amended out or canceled claims directed to inventions of Groups XI-XVII, XLVIII-XXXIV and XXVIII-LX, so these groups are not under consideration. The remaining groups currently under consideration are summarized briefly as follows:

> Groups I-X, directed to polypeptides.

Groups XVIII-XXVII, directed to polynucleotides encoding the polypeptides.
Groups XXXV-XLVII, directed to methods of using the polypeptide for binding a target molecule.
Group LXI, directed to an oligonucleotide.

According to MPEP 1893.03(d), unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. Independent claim 32 is included in and links all of Groups I-X.

In view of the latest claim amendment and upon consideration of the response filed 26 January 2004, the examiner has withdrawn the prior art rejections on the independent claim 32. Given that independent claim 32 now makes a contribution over the prior art, the lack of unity determination between Groups I-X is withdrawn.

Claim 23 links groups XXXV-XLVII and is dependent upon the product of Claim 32. Because the product makes a contribution over the prior art, the method of using the product also makes a contribution over the prior art and will now be rejoined.

Claim 16 links the products of Groups XVIII-XXVII. Claim 16 recites isolated nucleic acid comprising a nucleotide sequence encoding an effector domain of the binding molecule as claimed in claim 32. Because the broadest polynucleotide and polypeptide claims share a corresponding technical feature (the polynucleotide is required to encode the polypeptide) and because the polypeptide and the polynucleotide make a contribution over the prior art, the lack of unity determination between Groups I-X and Groups XVIII-XXVII is withdrawn.

Turning now to Group LXI, Claim 31 is directed to one of four oligonucleotides. The Petition states

> The primers of claim 31 are novel and inventive by virtue of the fact that they are adapted for use in the claimed methods and are in any case not suggested by the prior art. (page 3, fifth full paragraph)

It is noted that the oligonucleotides of Claim 31 have not been searched or examined by the Office. None-the-less, even if it were found to be true, applicant's argument that the primers are novel and not suggested by the prior art is not persuasive. The PCT Rules do not require unity of invention solely based upon novelty or obviousness. PCT Rule 13.2 requires a same or corresponding technical feature among the inventions. A comparison of the oligonucleotides of Claim 31 with the polynucleotides of Claim 16 shows a lack of a same or corresponding technical feature. The nucleic acid molecules of Group LXI fail to share a significant structural feature with the polynucleotides of Groups XVIII-XXVII. Moreover, these nucleic acid molecules fail to share a common property or activity with the polynucleotides of Groups XVIII-XXVII. The oligonucleotides cannot encode the polypeptides of Groups I-X. Nor can the oligonucleotides be used in the methods of Groups XXXV-XLVII. The argument that the primers are adapted for use in the claimed methods is not commensurate in scope with the claims. There are not method claims requiring the primers. Thus Group LXI lacks a same or

corresponding special technical feature with the products or methods under examination. For these reasons, the lack of unity determination is maintained between Group II and Group LXI.

DECISION

Applicant's petition to withdraw the lack of unity requirement is **GRANTED-IN-PART** for the reasons set forth above.

The lack of unity determination between Group II and Groups I, III-X, XVIII-XXVII, and XXXV-XLVII has been withdrawn.

The lack of unity determination between Groups II and LXI stands.

The application will be forwarded to the Examiner for consideration of the amendments and response filed 26 January 2004 and preparation of a supplemental Office action consistent with this decision.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600.

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